The Examiner stated the Lu et al. reference teaches a pacing system with an external programmer that can be used for the purpose of avoiding fusion beats. The Examiner stated the Lu et al. reference also teaches a pacing test that averages capture signals to create a threshold value, this test being executed in a loop. The Examiner stated it would have been obvious to a person of ordinary skill in the field of pacemaker design to combine the teachings of Kieval et al. '620 and Lu et al. to produce a heart stimulator that uses the average amplitude of evoked responses in detecting fusion beats. The Examiner stated it would have been obvious to such a person of ordinary skill to modify the system of Kieval et al. '620 by implementing an averaging test as taught by Lu et al. because, according to the Examiner, this would enhance the effectiveness of the system's ability to detect fusion beats.

Applicants note with appreciation that claim 19 was stated to be allowable if rewritten in independent form. Applicants respectfully traverse the above rejection, however, and therefore claim 19 has been retained in dependent form at this time.

In summary, it is Applicants' position that the testing loop disclosed in the Lu et al. reference has absolutely nothing to do with detecting the occurrence of fusion beats or an insipient infusion AV-interval and moreover, the individual steps of the testing loop disclosed in the Lu et al. reference do not correspond to the language of independent claim 14 of the present application.

The Examiner cited language at column 3, lines 19-22 of the Lu et al. reference as a teaching that the programmer can be used for the purpose of avoiding fusion beats. This language in the Lu et al. reference, however, is not a teaching for a procedure for detecting the occurrence of fusion beats, but is a statement that the programmer will cause the pacemaker to be operated in a particular mode with a short AV delay (namely the VVI or the DDD mode) rather than the conventional VOO mode, when the aforementioned testing loop is being executed. The reason for doing so, as noted by the Examiner, is to avoid competition or fusion beats, however, this is not a general statement of a way to set the pacer operation for long-term

avoidance fusion beats, but is merely a statement that such fusion beats will be avoided, when the test loop is being run, by temporarily switching the pacemaker to a mode of operation with a short AV delay. This is also described at column 4, lines 5-23.

The testing loop that is implemented in the pacemaker disclosed in the Lu et al. reference, after a mode switch has been made so that the pacemaker is operated in the VVI or DDD mode, has nothing whatsoever to do with determining or setting the AV delay that is used, or should be used, in those modes, nor in the conventional VOO mode. The testing loop disclosed in the Lu et al. reference is solely for improving the ability to detect capture, as stated at column 4, lines 41-43 of the Lu et al. reference, and as is clear from Figure 3 of that reference. In Figure 3, the final results of the loop are either to calculate the capture threshold in step 118 or to recalculate the capture threshold in 124. There is no teaching whatsoever that this threshold has any relationship to the AV interval or the detection of fusion beats.

Therefore, even if the Kieval et al. '620 reference were modified in accordance with the teachings of Lu et al., the most that can be said for such a combination is that the testing loop in Lu et al. could be used in the Kieval et al. '620 pacemaker to set the capture threshold to an appropriate level. Even if this were done, however, nothing would be changed in the Kieval et al. '620 reference regarding the detection of fusion beats, or with regard to the reaction of the Kieval et al. '620 system if an unacceptable number of fusion beats is detected.

Moreover, the actual details of the testing loop disclosed in the Lu et al. reference do not correspond to the language of claim 14 of the present application. Claim 14 states that an average amplitude value of the detected evoked response signal is formed for each cardiac cycle. These average amplitude values exhibit a variability from cardiac cycle-to-cardiac cycle. The average amplitude value for each cardiac cycle thus is compared in a comparator with a predetermined variability limit. Claim 14 further states that if the result of the comparison indicates that the variability limit was exceeded,

it is assumed that an insipient AV-interval is present. In response, the control unit shortens the AV interval used for pacing.

In the subject matter of claim 14, therefore, it is the *variability* of the average signal that is used as the basis for the aforementioned comparison. This has nothing whatsoever to do with setting the threshold level for determining ventricular capture, which is the purpose of the testing loop disclosed in the Lu et al. reference.

As explained in the passage cited by the Examiner in Lu et al. at column 5, lines 15-65, in the Lu et al. testing loop, integrals (not averages) of successive test pulses are compared. The only average that is formed takes place if the integrals are determined to be similar, as described at column 5, lines 10-19. If this is the case the average of the two integrals is then used to establish an initial capture threshold for subsequent ventricular pacing pulses.

Therefore, there is no comparison of averages that takes place in the Lu et al. testing loop, and there is no comparison of the variability of such an average with regard to a threshold, in order to determine the occurrence of an insipient fusion AV-interval, as set forth in claim 14.

Therefore, since the testing loop in the Lu et al. reference has nothing whatsoever to do with detecting fusion beats, or setting an AV-interval dependent on the occurrence of fusion beats, a person of ordinary skill in the field of pacemaker design would have no reason whatsoever to modify the Kieval et al. '620 pacemaker in accordance with the teachings of Lu et al., for the purpose of allegedly improving the ability to detect fusion beats or to respond thereto. Moreover, even if such a combination were made (for reasons unknown to the present Applicants) this still would not result in a pacemaker operating according to the language of claim 14.

Claim 14, therefore, would not have been obvious to a person of ordinary skill in the field of pacemaker design under the provisions of 35 U.S.C. §103(a) based on the teachings of Kieval et al. '620 and Lu et al.

Claims 15-18, 20 and 21 add further structure to the non-obvious combination of claim 14, and are therefore patentable over the teachings of the aforementioned references for the same reasons discussed above in connection with claim 14.

All claims of the application are therefore submitted to be in condition for allowance, early reconsideration of the application is respectfully requested.

Submitted by,

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